From: (b) (6)
To: Chuong, Bao; McGhee-Lenart, Renee
Subject: follow-up items from interview
Date: Wednesday, April 3, 2019 12:16:02 PM
Attachments: (b) (5), (b) (6)

(b) (5), (b) (6)

FW: EtO Pager for Mike K and DDs 08 01 17.docx

Sent: Tue 8/1/2017 4:23:57 PM

From: Lassiter, Penny
To: Lavoie, Tegan
CC: Shine, Brenda, Diem, Art, Bouchard, Andrew, Carey, Angela

EtO Pager for Mike K and DDs 08 01 17.docx

FYI,

Penny Lassiter
Group Leader
Refining and Chemicals Group
SPPD/OAQPS
U.S. Environmental Protection Agency
Mail Code: E143-01
Research Triangle Park, NC 27711
(919) 541-5396
lassiter.penny@epa.gov

From: French, Chuck
Sent: Tuesday, August 01, 2017 11:49 AM
To: Cozzie, David <Cozzie.David@epa.gov>; Lassiter, Penny <Lassiter.Penny@epa.gov>
Subject: FW: EtO Pager for Mike K and DDs 08 01 17.docx

From: Rimer, Kelly
Sent: Tuesday, August 1, 2017 11:34 AM
To: French, Chuck <French.Chuck@epa.gov>; Shrager, Brian <Shrager.Brian@epa.gov>; Goehl, Eric <Goehl.Eric@epa.gov>
Subject: EtO Pager for Mike K and DDs 08 01 17.docx

FYI here is the EtO pager for today.

Thanks,
Kelly

Ethylene Oxide (EtO) Update
August 1, 2017

Summary:

- In December 2016, ORD released the IRIS assessment for the carcinogen ethylene Oxide (EtO). EtO is now known to be approximately 60 times more potent than previously understood. It is a known human carcinogen.
- We have completed one RTR that includes significant emissions of EtO – Commercial Sterilizers. The 2007 rule estimated cancer risks at 90-in-1 million, which we determined to be acceptable. Given this result and the updated IRIS value, we are working to better characterize more current emissions and potential risks from EtO in the 2014 NATA.
- The draft 2014 NATA results indicate that 42 EtO-emitting facilities may significantly contribute to census tract-level cancer risks greater than 100-in-1 million. We are continuing to QA emissions from these facilities, and are requesting that SPPD assist in characterizing EtO emissions.
- A sub-group of the EPA's Air Toxics Risk Assessors (ATRA) has been formed to allow the Regions to share information and work together. We are on the calls with this group.
- We list proposed follow-up actions below.

IRIS Assessment:

- In December 2016, IRIS released a new assessment for EtO with a revised unit risk estimate (URE).
- EtO is a known human carcinogen; it causes cancers of the reproductive and immune systems in humans by the inhalation route of exposure.
- EtO is also known to be mutagenic and to cause chromosome damage. This makes EtO of particular concern for children because they may be more susceptible to harmful effects and because genetic mutations that occur early in life have the potential to be passed on to offspring.
- The revised URE (3×10^{-3} per $\mu g/m^3$) is about 60 times greater than the URE we had been using for risk assessments (California EPA URE of 8.8×10^{-5} per $\mu g/m^3$), indicating that EtO is a much more potent carcinogen than previously thought.
  - The revised IRIS URE is based on human data from a NIOSH study (Steenland et al., 2003; Steenland et al., 2004).
  - Confidence in the URE is considered "relatively high."
- The 2014 NATA uses this revised URE, as does any RTR modeling conducted since January 2017.

Ethylene Oxide Sterilizer MACT for Major and Area Sources:

- Finalized in 2006, the EtO Sterilizer RTR did not revise the original MACT standard, which was promulgated in 1994.
  - "…the maximum individual cancer risk for this source category already meets the level we generally consider acceptable, and that further control requirements would achieve, at best, minimal emission and risk reductions at a very high cost from emission vents controlled with MACT at both major and area sources."
  - 76 facilities (both major and area) included in the assessment. Only assessed EtO, which was the only HAP emitted.
  - Used the Cal EPA URE (8.8×10^{-5} per $\mu g/m^3$).
  - Maximum cancer risk = 90-in-1 million. Total cancer incidence = 0.04.

- In a comment response during the rulemaking process we noted, "We have the authority to revisit (and revise, if necessary) any rulemaking if there is sufficient evidence that changes within the affected industry or significant improvements to science suggests the public is exposed to significant increases in risk as compared to the risk assessment prepared for the rulemaking (e.g., CAA section 301)."
- Also in a comment response, "EPA is currently developing an updated cancer assessment for ethylene oxide… The EPA cancer assessment will not receive external peer review until mid-2006, which is after the promulgation date of the residual risk rule for this source category. Our authority to revisit any rulemaking is addressed in Section III.1." (see above)

- There is also a hospital ethylene oxide sterilizer area source NESHAP. Promulgated December 2007.

EtO Facility Review in Draft 2014 NATA:

- We provided the draft 2014 NATA results for point sources to the states, with updated EtO risks, in January 2017. The review period for this data ended on June 1, 2017. Staff in AQAD are currently processing all revisions provided during that time and working with Regions and S/L/T on any needed follow up discussions.
- For the 42 "priority list" facilities where cancer risks are driven by EtO, emissions for 41 of the facilities have been verified by state agency data submitters or by the TRI program:
  - 30 – confirmed no changes
  - 11 – changes, though some are small emissions or release point changes
  - 1 – still confirming with R4, KY
- In June 2017, we released the full risk results and emissions profiles for all source categories (including point, non-point, and mobile) to S/L/T for review of the draft 2014 NATA. We are approaching the end of the S/L/T review period (August 11, 2017) and without additional information, emissions at about 80% of these facilities will remain unchanged. We propose a series of additional actions to better understand the potential for elevated risks from ethylene oxide emissions. See last section below for recommended actions.

EtO Emission Levels and Sources in Draft 2014 NATA:

- In the 2014 NEI there are 702 facilities with emissions of 176 tons
- The 42 "priority" facilities emit 148 tpy before correction and 139 tpy after correction
  - 35 are reported by state or local agencies; 7 are from TRI
- Types of facilities on "priority" list:
  - 14 unique NAICS: chemical manufacturing, medical equipment manufacturing, packaging/labelling, and hospitals.
  - 21 chemical manufacturers: 3 Union Carbide, 2 Shell, others include Dow and BASF
  - 13 medical equipment manufacturers and packaging/labelling facilities; For example, 3 are owned by Sterigenics, a global leader in outsourced contract sterilization services and 2 are owned by Midwest Sterilization, another contract company
  - 7 hospitals
    - 4 of them have been revised to 0 tpy or significantly lower than originally reported
    - 2 discontinued the use of EtO, but after 2014 inventory reported
    - 1 (in Pittsburgh) was reviewed and not changed.

- Emission point types at "priority" list facilities:
    - Often, the EtO emissions at these facilities are calculated via engineering judgement. In other cases, material balance or emission factors are used.
    - The control efficiency assumptions could make a large difference in the estimate. (For example, at one facility, an outdated OSHA limit value of 50 ppmv was used, while the new value is 5 ppmv.)
    - For the 42 facilities, roughly half of the emissions are emitted from stacks and half are fugitives.

The Air Toxics Risk Assessors (ATRA) have formed an EtO sub-group to share information and work together.

- This group, led by Carol Bellizzi (R2) and Margaret Sieffert (R5), meets every couple weeks.
- They want to ensure consistency when conducting outreach and, if necessary, developing options for reducing EtO emissions.
- Regions have begun briefing their management on the magnitude of the EtO situation and how our NATA schedule and release of information may not be as fast as they would like.

Proposed Follow-up Actions:
For the 42 "Priority List" Facilities:

- QA the emission point and census block locations. (HEID/ATAG)
- Review and QA the emissions, stack parameters, etc.; Contact facilities, if needed, to obtain information. (SPPD/RCG, SPPD/FIG)
- Incorporate any revisions into EIS for v2 of 2014 NEI and v2 of 2014 NATA. (AQAD/EIAG)

Proposed Follow-up Actions:
For the 42 "Priority List" Facilities:

- QA the emission point and census block locations. (HEID/ATAG)
- Review and QA the emissions, stack parameters, etc.; Contact facilities, if needed, to obtain information. (SPPD/RCG, SPPD/FIG)
- Incorporate any revisions into EIS for v2 of 2014 NEI and v2 of 2014 NATA. (AQAD/EIAG)

Additional Actions:

- Develop/improve the sampling method for EtO such that detection levels in ambient air are at concentrations around or below health levels of concern (AQAD/MTG, AQAD/AAMG)
    - Chronic exposure concentrations of 0.2 ng/m^3 relates to 1-in-1 million
    - Chronic exposure concentrations of 20 ng/m^3 relates to 100-in-1 million
- Determine approach to QA/QC emissions from all EtO emitting facilities in 2014 NEI with potential elevated risks at block level.
- Coordinate with regions as appropriate.

For areas that continue to have elevated risks for EtO:

- Working with the regions, develop an outreach and communication strategy for affected areas. (HEID/AQAD/SPPD/PACS).
- Consider timing of communications relative to NATA release (scheduled for Spring 2018).